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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

August 4, 2000

E. EDWARD KAVANAUGH
PRESIDENT

BY HAND DELIVERY

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Re: Docket No. 78N-0038
Sunscreen Drug Products for Over-the-Counter Human Use

On behalf of its members, The Cosmetic, Toiletry, and Fragrance Association (CTFA), submits these comments in partial response to the Food and Drug Administration's (FDA's) reopening of the administrative record on sunscreen drug products for over-the-counter (OTC) human use. Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; Extension of Effective Date; Reopening of Administrative Record. 65 Fed. Reg. 36319 (June 8, 2000).

CTFA is requesting that as part of the reopening of the administrative record on sunscreens, FDA consider additional labeling issues relating to such products that are raised by FDA's general requirements for OTC drug labeling. Specifically, CTFA requests that FDA revise the final sunscreen monograph to permit modifications to certain requirements of the OTC labeling content and format rule applicable to sunscreens under 21 C.F.R. § 201.66. While CTFA will be submitting additional comments to FDA on the specific issues raised in the June 8, 2000 notice, we believe

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request of FDA. The Agency believes that the appropriate way to modify the impact of the OTC Drug Labeling Regulation on any one product category is through modification of the specific regulation or monograph for that category.

This comment is not intended to change the labeling regulations already promulgated by FDA with respect to sunscreen products marketed as a lipstick and "products labeled for use only in specific small areas of the face (e.g., lips, nose, ears, and/or around eyes)" contained in 21 C.F.R. Sec. 352.52 and promulgated at 64 Fed. Reg. 27688-89 (May 21, 1999.) We believe those modifications to the OTC Drug Labeling Regulation are appropriate. This document proposes additional modifications of that rule that would establish the maximum required labeling under the OTC Drug Labeling Regulation for all other sunscreens.

This document is not CTFA's final comment on issues raised by the Final Monograph for Sunscreen Drug Products. Additional comments are being prepared by CTFA and by individual companies that will address sunscreen testing requirements, permissible claims, indications for use, directions for use, and other labeling, testing and formulation requirements. Those comments will be filed prior to the September 6, 2000 deadline established when the Agency reopened the public record of the Final Monograph for Sunscreen Drug Products for further comment.

It should be noted that the proposals in CTFA's future comments would change the content of the OTC drug label for sunscreens but would not change the required format for presenting the information in labeling if the following comments are accepted. For example, in comments to be filed at a later date, CTFA will propose additional indications for use for sunscreens which a manufacturer may choose to use in lieu of or in addition to currently allowed indications if appropriate for their particular product.

benefited consumers and should not be unnecessarily discouraged by new labeling requirements that could make it impossible to produce these products in convenient, easy-to-transport package sizes. Packaging innovations now make all of these products easy to carry and use by an increasingly mobile population. Smaller packages increase the likelihood that consumers will carry sunscreens with them and apply the product in the many different situations where they are exposed to UV radiation.

Finally, during the years of the OTC Drug Review, medical and public health authorities have come to understand and emphasize the many benefits of sunscreens to protect against sunburn, skin aging and skin cancer. Many agencies and medical authorities such as the FDA, Centers for Disease Control and Prevention, American Cancer Society, American Academy of Dermatology and the Skin Cancer Foundation have stressed the importance of sun protection. This includes the use of sunscreens in reducing the threat of skin cancer and one of its most dangerous forms, malignant melanoma.

Overview of CTFA's Request and Underlying Rationale

As described in detail below, CTFA is requesting that FDA modify the labeling format and content requirements of 21 C.F.R. § 201.66 as they apply to sunscreens in a manner that will permit greater flexibility in the presentation of such information. According to FDA, the substantial labeling changes required by the Final OTC Labeling Rule are intended to enable consumers to better read and understand OTC drug product labeling and to apply this information to the safe and effective use of OTC drug products. CTFA continues to maintain, however, that FDA has failed to adequately articulate its basis for imposing many of the requirements of the Final OTC Labeling Rule on sunscreen and other cosmetic-drug product labels. Indeed, nowhere in the rulemaking process has FDA sufficiently considered or distinguished between OTC drug products that raise the safety and consumer confusion concerns addressed by the Final OTC Labeling Rule and cosmetic-drug products with no dosage limitations that do not raise the concerns relied upon by FDA to support the new labeling requirements.

containing sunscreen), minimal information is needed for the safe and effective use of the product.

64 Fed. Reg. 13270. FDA listed the typical characteristics of products requiring minimal information for their safe and effective use as follows:

- packaged in small amounts;
- having a high therapeutic index;
- carrying extremely low risk in actual consumer use situations;
- providing a favorable public health benefit;
- requiring no specified dosage limitation; and
- requiring few specific warnings (*e.g., Reyes syndrome*) and no general warnings (*e.g.*, pregnancy or overdose warnings).

Id. The agency indicated its intent to "identify products with these characteristics" and "consider appropriate exemptions in their respective monographs and drug marketing applications to the extent possible." Id. CTFA believes that sunscreens fit sufficiently within the parameters of the above criteria to justify the labeling modifications requested herein.

Sunscreens have a high therapeutic index in that their effective dose is substantially lower than the dose that would pose even a minimal risk of toxicity.

Sunscreens carry extremely low risk in actual consumer use situations. Sunscreens have a decades-long history of safe use because they have a low toxicity profile and because consumers have a clear understanding of when and how to use these products. Only minimal information is necessary to ensure the safe and effective use of sunscreens. (It is noteworthy that sunscreens are not considered drugs and are regulated as cosmetics in Europe and most other parts of the world.)

manner, the ability of consumers to select and use sunscreens properly. The underlying records for the Final OTC Sunscreen Rule and the Final OTC Labeling Rule fully support CTFA's proposed sunscreen label and the changes requested by CTFA warrant serious consideration by FDA.

Procedural History

The Sunscreen Monograph

FDA has already published a partial final monograph addressing many of the requirements relevant to the conditions under which OTC sunscreen drug products bearing UVB claims will be generally recognized as safe and effective and not misbranded. 64 Fed. Reg. 27666 (May 21, 1999) (hereinafter the "Final OTC Sunscreen Rule"). The Final OTC Sunscreen Rule includes modifications to the general OTC drug labeling rules in 21 C.F.R. § 201.66, to accommodate sunscreen products labeled for use on small areas of the face and as lipsticks.

In response to a Request for Stay and Citizen Petition filed by CTFA on April 15, 1999, FDA stated in an October 1, 1999, decision that it would delay the effective date for the Final OTC Sunscreen Rule until December 31, 2002, while important conditions relating to both UVA and UVB radiation protection are resolved. Most recently, on June 8, 2000, FDA issued a Federal Register notice, in response to which these comments are being filed. That notice alerted the public of its decision to delay the effective date of the Final OTC Sunscreen Rule and reopening the administrative record on sunscreens to permit comment on monograph issues. (65 Fed. Reg. 36319 [June 8, 2000])

The Final OTC Labeling Rule

Prior to publishing its Final OTC Sunscreen Rule, FDA published a final rule establishing standardized content and format requirements for the labeling of all OTC drug products. 21 C.F.R. § 201.66. Over-the-Counter Human Drugs; Labeling Requirements; Final Rule. 64 Fed. Reg. 13254 (March 17, 1999) (hereinafter the "Final

applicable to all OTC drug products, category-specific arguments may be addressed within the context of individual product monographs.[3] FDA officials have repeatedly advised CTFA that this is the appropriate way to address changes in the OTC Drug Labeling Regulation that are necessary for specific product categories. As described in the following section, sunscreens represent a unique OTC drug category for which the labeling modifications requested by CTFA are appropriate both as a matter of public health and law.

Flexible Labeling for Sunscreen Products is Justified

It is universally recognized that excessive exposure to the ultraviolet rays of the sun can produce a wide variety of adverse health consequences. Effects range from immediate burning of the skin, to premature aging, wrinkling, and other damage to the skin, to various types of skin cancers including malignant melanoma (a very serious form of skin cancer that has increased in the past several years). As awareness of the sun's damaging effects has increased, public health authorities (including FDA and NIH), dermatologists, and other health organizations (the American Academy of Dermatology and American Medical Association) are urging consumers to use products containing sunscreens regularly, on a daily basis, rather than only when they expect to be exposed to intense sunlight situations. See CTFA's comments to the TFM for OTC Sunscreens, Docket No. 78N-0038, at 4-5 (March 21, 1994). Thus, sunscreen products are substantially different from most other types of OTC drug products in that they are recommended for use on a daily basis for persons who have no illness, as a means of preventing serious disease in the future.

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[3] While CTFA continues to believe that many of the arguments that support the modifications proposed herein should apply across the board to all five of the personal care drug product categories identified in prior comments (i.e., antiperspirants, skin protectants, antidandruff products, and antimicrobial soaps and washes), for purposes of these comments CTFA is limiting the scope of its requests at this time to OTC sunscreen products. CTFA reserves the right to raise this issue once again or in the context of the individual monographs for the other four personal care product categories identified directly above. CTFA believes that its proposals for sunscreen products establish sound principles that should be applied to all categories meeting the appropriate criteria.

FDA's concerns about increased consumer self-diagnosis and self-medication do not apply to sunscreen products. Sunscreens are widely used by consumers and sufficiently labeled for safe and effective use under current OTC drug and cosmetic labeling requirements. To the extent their use by consumers reflects any of the changing patterns of use identified by FDA in its proposal, such changes are precisely those that FDA and public health officials are encouraging for sunscreen use. For example, to the extent sunscreen use can be characterized as self-medication by consumers or as presenting opportunities for increased use by the elderly, a wide array of public health agencies and experts aggressively promote such uses. Indeed, in contrast to traditional OTC drug therapies, the concern with regard to sunscreens is product *under* use rather than *over* use.

FDA's concerns regarding the possibility of inappropriate use by the elderly and of increased adverse reactions and misuse of OTC drug products also do not apply to consumer use of sunscreen products. Sunscreens have an exceptional safety record and have been used by consumers of all ages for more than two decades with an extraordinary safety record. Rather than concerns about the overuse of sunscreens, the American Academy of Dermatology and other consumer groups have expressed concern (i) that consumers do not use enough sunscreen; and (ii) that many consumers do not understand the importance of protection from everyday UV exposure afforded by products such as cosmetic moisturizers containing sunscreen ingredients. In practical terms, the dangers of exceeding the "recommended dosage" associated with some categories of OTC drugs simply do not exist for sunscreens. Additionally, adverse reactions associated with sunscreen use are generally limited to mild rashes and other skin irritations, for which warning information is included in CTFA's proposed sunscreen label.

Despite the fact that the safety and consumer confusion concerns and the changing patterns of OTC drug use cited by FDA are not relevant to sunscreens, CTFA's proposed label incorporates a majority of the labeling requirements imposed under the Final OTC Labeling Rule. Consequently, CTFA believes that a good faith review of the labeling modifications it is requesting for sunscreen products, measured against the agency's rationales for standardizing the format and content of OTC drug

vast majority of OTC drug products. Rather, modifications of the nature sought by CTFA for sunscreens are specific to that monograph and rely on rationales that transfer easily only to the very small number of OTC drugs in the personal care product categories that CTFA has identified above. Moreover, CTFA has designed its proposed labeling to retain as many features of the new OTC drug label as feasible.

FDA's Proposed Sunscreen Label

Under FDA's Final OTC Sunscreen Rule, all sunscreen products (other than those intended for use on small areas of the face and as lipsticks) would be labeled in accordance with the following model:

Drug Facts
Active ingredients ***Purpose*** Octyl methoxycinnamate (5%).....Sunscreen Phenylbenzimidazole sulfonic acid (4%)
Uses • helps prevent sunburn • higher SPF gives more sunburn protection
Warnings For external use only
When using this product • keep out of eyes. Rinse with water to remove.
Stop use and ask a doctor if • rash or irritation develops and lasts
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions • apply liberally before sun exposure and as needed • children under 6 months of age: ask a doctor
Inactive ingredients water, isohexadecane, glycerin, butylene glycol, triethanolamine, stearic acid, cetyl alcohol, cetyl palimate, DEA-cetyl phosphate, aluminum starch octenyl succinate, titanium dioxide, imidazolidinyl urea, methylparaben, propylparaben, carbomer, acrylates/c10-30 alkyl acrylate crosspolymer, PEG-10 soya sterol, disodium EDTA, castor oil, fragrance, red 4, yellow 5.

NOTE: This sample is intended to provide a "picture" of the new label and does not necessarily reflect type size, leading or other technical format requirements. No attempt has been made to distinguish between the thickness of barlines and hairlines. Additional or alternate language for indications and directions for use will be recommended by separate comment on the Final Sunscreen Monograph.

Side-By-Side of the FDA and CTFA Proposals

Drug Facts
Active ingredients **Purpose** Octyl methoxycinnamate (5%).....Sunscreen Phenylbenzimidazole sulfonic acid (4%)
Uses • helps prevent sunburn • higher SPF gives more sunburn protection
Warnings For external use only
When using this product • keep out of eyes. Rinse with water to remove.
Stop use and ask a doctor if • rash or irritation develops and lasts
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away
Directions • apply liberally before sun exposure and as needed. • children under 6 months of age: ask a doctor
Inactive ingredients water, isohexadecane, glycerin, butylene glycol, triethanolamine, stearic acid, cetyl alcohol, cetyl palimate, DEA-cetyl phosphate, aluminum starch octenyl succinate, titanium dioxide, imidazolidinyl urea, methylparaben, propylparaben, carbomer, acrylates/c10-30 alkyl acrylate crosspolymer, PEG-10 soya sterol, disodium EDTA, castor oil, fragrance, red 4, yellow 5.

Active Ingredients.....Octyl methoxycinnamate (5%)
Phenylbenzimidazole sulfonic acid (4%)

Use helps prevent sunburn

Warnings

- Keep out of eyes.
- Stop use if skin rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • apply liberally before sun exposure and as needed
• children under 6 months of age: ask a doctor

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Inactive Ingredients. Optional disclosure provided at other location on label or in labeling accompanying the product as follows:

Inactive ingredients water, isohexadecane, glycerin, butylene glycol, triethanolamine, stearic acid, cetyl alcohol, cetyl palmitate, DEA-cetyl phosphate, aluminum starch octenyl succinate, titanium dioxide, imidazolidinyl urea, methylparaben, propylparaben, carbomer, acrylates/c10-30 alkyl acrylate crosspolymer, PEG-10 soy sterol, disodium EDTA, castor oil, fragrance, red 4, yellow 5.

unnecessary required wording); and (2) modifications permitted for small packages under the Final OTC Drug Labeling Rule (format changes). Both of these mechanisms may legitimately be applied to all types of OTC sunscreen products. As detailed below, FDA's Final OTC Sunscreen Rule provides for modifications to sunscreens formulated as lipsticks and for small areas of the face. CTFA strongly supports the modifications permitted by FDA under those circumstances. Because, however, all sunscreens are personal health care products that are critical to preventing serious medical conditions, have become well known to consumers over several decades of use, and have no record regarding either consumer confusion or safety problems, CTFA believes that many of the modifications sanctioned by FDA for lipsticks and products labeled for use only on small areas of the face should apply to all sunscreen products.

CTFA's Proposed Content Changes

As discussed above, sunscreen drug products present virtually none of the concerns that formed the basis for the Final OTC Labeling Rule. Moreover, FDA has already adopted many of CTFA's proposed changes for lipsticks and sunscreen products labeled for use only on small areas of the face. Thus, with respect to those changes, FDA has already concluded that there is no underlying public health risk to CTFA's proposed label as applied to sunscreen products. CTFA's proposed sunscreen label would provide a consistent format for all products in this particular category and would include only modest revisions from the requirements imposed on all other OTC drug product labels.

Among FDA's motivations in establishing standardized content requirements for all OTC drug product labels is to enable consumers to better read and understand important drug information to ensure the safe and effective use of such product. CTFA's proposed modifications to the content requirements set forth at 21 C.F.R. § 201.66(c) and at 21 C.F.R. § 352.52, designed to apply to all OTC sunscreen products, will not compromise that goal.

FDA noted in the preamble to the final rule on the OTC label format that, in one of the labeling studies that FDA conducted in conjunction with the OTC label format rule, "Evaluation of Revised Formats for Over-the-Counter (OTC) Drugs" ("Study B"), indicated that in consumer preference tests, consumers preferred OTC labels that contained a title. Of course, a consumer preference does not mean a title is essential to accomplishing FDA's stated goals of ensuring full consumer understanding of product information. Based on the long history of safe use of sunscreens, we believe consumers already fully understand how to use such products safely and effectively and that including a title for the required information is unnecessary.

In addition to being unnecessary, the "Drug Facts" title is inappropriate on sunscreen products that also provide cosmetic benefits. Besides their drug purposes, such products also have legitimate, beneficial cosmetic purposes which are equally recognized under the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. §§ 321 et seq. "Drug Facts" inappropriately denotes a single purpose to a product that provides a dual benefit. Removing the "Drug Facts" title is a reasonable accommodation to address the issue, particularly in light of the fact that it does not undermine the agency's labeling goals. By simply removing the "Drug Facts" title, the critical information that must be contained in a sunscreen label will continue to clearly and legibly appear.

Eliminate Purpose Heading and Associated Information

CTFA's proposed sunscreen label does not include a "Purpose" heading or the "sunscreen" statement that would accompany that heading. CTFA believes that requiring such information is unnecessary in that it is duplicative of both the statement of identity requirement for the principal display panel of sunscreen products and of the "Use" statement immediately proceeding the listing of active ingredient information. FDA has already recognized that reiterating the purpose information in the required format is not necessary for sunscreen drug products in smaller packages and intended for use on small areas of the face and as lipsticks. 21 C.F.R. § 352.52(f)(1). Similar

be presented as follows:

> Keep out of eyes.
> Stop use if skin rash occurs.

CTFA believes that the currently required subheading information and warning language is not necessary for full consumer understanding of the warning information, or for the otherwise safe and effective use of sunscreen products. The warning information relayed by CTFA's proposed sunscreen label, which compresses four lines into two, is substantively the same as that provided by the separate subheadings and retains the hierarchy of FDA's preferred format. Moreover, FDA's modifications for sunscreen products labeled for use on small areas of the face adopt the identical format and content for presenting the warning information. 21 C.F.R. § 352.52(f)(1)(iv). Presumably in allowing such modification FDA felt comfortable that necessary warning information was adequately conveyed. CTFA believes that similar modifications should apply to all sunscreen drug products.

Move Listing of Inactive Ingredients to Labeling at Point of Sale

In addition to the substantive content changes suggested above, CTFA proposes to allow, as an option, the relocation of inactive ingredient information from the label, to labeling at the point of sale. CTFA previously has proposed that FDA provide the same flexibility to OTC drug products currently afforded to cosmetic products, by allowing ingredient information to be included in labeling "accompanying the product" if the package has a total surface area of less than 12 square inches and is not enclosed in an outer container. See 21 C.F.R. § 701.3(i).

CTFA believes that FDA has the authority to provide similar flexibility to OTC drug products under section 412(c) of the FDA Modernization Act of 1997 (FDAMA). Section 412 amended the misbranding provisions of the FD&C Act to require that a drug will be misbranded unless its label bears, among other things, "the established name of

> This final rule provides a format for presenting information that will allow consumers to readily distinguish among seemingly similar products and to readily access important drug information.

64 Fed. Reg. 13254 and 13270. More recently, FDA summarized the benefits of the required format as follows:

> The new format establishes a clear, easy-to-read presentation that lists the required information in a logical hierarchy, with simple headings and subheadings to introduce major sections of the labeling. The format also includes minimum type size and graphical standards, to help ensure that consumers are able to read the required labeling comfortably, from beginning to end. And, the format is designed to allow consumers to compare similar products side-by-side, to help them recognize the differences among products, and to help them select the best product to meet their needs.

Letter from William K. Hubbard to E. Edward Kavanaugh of CTFA (February 4, 2000).

CTFA's proposed sunscreen label in no way diminishes the power of the format devised by FDA. Indeed, the vast majority of the standard format requirements set forth in 21 C.F.R. § 201.66(d) are preserved in CTFA's proposed sunscreen label. As noted above, CTFA's proposed sunscreen label would not change any of the following format-related requirements:

- Use of upper and lower case letters;
- Left justification of information;
- Type size;
- Use of bold and italic type; and
- Use of bullets.

Of the format changes that CTFA is suggesting, most have already been adopted by FDA for some OTC drug product labels. Extending those modifications more broadly across the entire sunscreen product category will not compromise FDA's goal of presenting the information consumers need in an easy to understand and identifiable manner.

Reg. at 13270. Sunscreens have high therapeutic indices, are extremely low risk, provide a favorable public benefit, require no specified dose limitations and require few specific warnings and only one general warning. Even in light of the low risk nature of the product, elimination of the requirement for a box enclosure in no way reduces the amount of information available to the consumer. Accordingly, given the nature of sunscreen products combined with the fact that the box enclosure is not essential and its elimination will in no way reduce the amount of information available to consumers, CTFA requests that it be eliminated for all OTC sunscreen products.

Eliminate the Requirement for Barlines and Hairlines

For the many of the same reasons that the requirement for a box should be eliminated, we also believe that the use of barlines and hairlines as part of the OTC label format should not be required for any sunscreen product. FDA already has recognized that these may be eliminated for lipsticks and sunscreen products labeled for use only on small areas of the face. For the flexible labeling that we also believe to be appropriate for all sunscreens, we do not believe that the barlines or hairlines are necessary to make the required information understandable by the consumer. Moreover, this requirement would add significantly to the space required for the label and would reduce the options available for smaller, more portable package sizes for these products.

Eliminate the Heading and Information Related to the "Purpose" of the Product

Although addressed more fully above as a proposed content change, CTFA's decision to eliminate the "Purpose" heading on sunscreen labeling does include a format component in that the heading and accompanying information would not be aligned to the right of the list of sunscreen active ingredients as required by 21 C.F.R. § 201.66(d)(6). Since, however, the Final OTC Drug Labeling Rule requires the purpose information to be included within the same horizontal barlines as the active ingredient information, the elimination of the heading in this manner would have only a minimal impact on the format of sunscreen labels. The hierarchy of information and

the initial date that the final requirements for labeling are known to the time the product is ready to be placed in the distribution chain, and takes into account the following activities:

- Understanding the new labeling regulations and assessing changes on existing labels
- Preparation of art and print work and review for regulatory compliance
- Printing and delivery of new labels

This time frame does not take into account the time that would be necessary if existing products also must be repackaged. Under the current FDA OTC Drug Labeling Regulation, many products would require new packages or would have to be discontinued. The design of entirely new packaging systems will add at least one year to the process. This process is even more challenging than designing new labels, and sufficient time must be allowed for the following requirements:

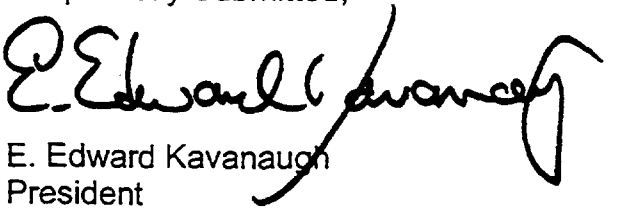
- Develop proposals that are consistent with consumer needs, retail space requirements and maintenance of the brand image and identity
- New Package Design
- Safety and Environmental Compliance Review
- Consumer Testing
- Execution of New Package Design

A unique feature of sunscreen marketing adds to the need for an expedited FDA decision on final labeling requirements for sunscreens. Typically, retailers return unsold "beach sunscreens" or seasonal products to manufacturers at the end of the season. These products are then redistributed at the beginning of the next season. Because relabeling existing product is frequently not a practical alternative, manufacturers need additional time to comply to minimize the need to destroy product that does not have compliant labeling (instead of being recycled to retailers during the following season.)

It is simply contrary to the public interest to impose unreasonable labeling requirements on sunscreens when there is no demonstrated problem with existing labeling. Ironically, the current regulations also will reduce the incentives to make sunscreen protection in a number of convenient, easy-to-use forms.

By granting CTFA's proposals to modify the labeling requirements, FDA can still gain the benefits of its new labeling format while preserving availability of products that benefit consumers and public health.

Respectfully Submitted,



E. Edward Kavanaugh
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